ATTACHMENT - REQUIRED STATE AGENCY FINDINGS

FINDINGS
C = Conforming
CA = Conditional
NC = Nonconforming
NA = Not Applicable

Decision Date: March 17, 2016
Findings Date: March 17, 2016

Project Analyst: Gloria C. Hale
Assistant Chief: Martha J. Frisone

Project ID #: F-11123-16
Facility: Carolinas Medical Center
FID #: 943070
County: Mecklenburg
Applicant: The Charlotte-Mecklenburg Hospital Authority
Project: Cost overrun for Project I.D. # F-10075-13 (renovate and consolidate acute care laboratory operations)

REVIEW CRITERIA FOR NEW INSTITUTIONAL HEALTH SERVICES

G.S. 131E-183(a) The Department shall review all applications utilizing the criteria outlined in this subsection and shall determine that an application is either consistent with or not in conflict with these criteria before a certificate of need for the proposed project shall be issued.

(1) The proposed project shall be consistent with applicable policies and need determinations in the State Medical Facilities Plan, the need determination of which constitutes a determinative limitation on the provision of any health service, health service facility, health service facility beds, dialysis stations, operating rooms, or home health offices that may be approved.

C

The applicant, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center (CMC), proposes a cost overrun for Project I.D. # F-10075-13 which authorized the hospital to renovate and consolidate its acute care laboratory operations. The original project, Project I.D. # F-10075-13, was approved for a capital cost of $3,754,728 and was scheduled to offer services by October 1, 2015. In Section VI.2, page 28, the applicant states that the project will now cost $4,794,728, an increase of $1,040,000 or 27.7% [(4,794,728/ $3,754,728) – 1 = 0.277 or 27.7%]. The applicant states, in Section X, page 46, that the project will be complete by April 1, 2017. There is no material change in scope from the originally approved project in this application.

Need Determination

The applicant does not propose to increase the number of licensed beds in any category, add any new health services or acquire equipment for which there is a need determination in the 2016 State Medical Facilities Plan (SMFP). Therefore, there are no need determinations in the 2016 SMFP that are applicable to this review.

Policies

Policy GEN-4: ENERGY EFFICIENCY AND SUSTAINABILITY FOR HEALTH SERVICE FACILITIES was applicable to Project I.D. # F-10075-13, and that application was consistent with Policy GEN-4. The applicant proposes no changes in the current application that would affect that determination.

There are no policies in the 2016 SMFP that are applicable to this review.

Conclusion

In summary, the applicant was previously approved to renovate and consolidate its acute care laboratory operations upon project completion. In Project I.D. # F-10075-13, the applicant was conforming to this criterion. The applicant proposes no changes in the current application that would affect that determination. Therefore, the application is conforming to this criterion.

(2) Repealed effective July 1, 1987.

(3) The applicant shall identify the population to be served by the proposed project, and shall demonstrate the need that this population has for the services proposed, and the extent to which all residents of the area, and, in particular, low income persons, racial and ethnic minorities, women, handicapped persons, the elderly, and other underserved groups are likely to have access to the services proposed.

C

The Charlotte-Mecklenburg Hospital Authority d/b/a CMC was issued a certificate of need (CON) on May 14, 2013 for Project I.D. # F-10075-13 which authorized the renovation and consolidation of CMC's acute care laboratory operations upon project completion. The original project was approved for a total capital cost of $3,754,728 and was scheduled to be complete by October 1, 2015. There is no material change in scope from the originally approved project in this application; the applicant states in Section II.3, page 11, that upgrades and changes in utility infrastructure necessitated by the proposed analyzer equipment for the lab, necessary changes to the layout of the space to best accommodate services, and unanticipated and rising construction costs are the reasons for the increased costs. In Section VI.2, page 28, the applicant states that the project will now cost $4,794,728, an increase of $1,040,000 or 27.7% [(4,794,728/ $3,754,728) – 1 = 0.277 or 27.7%]. The applicant states, in Section X, page 46, that the project will be complete by April 1, 2017.

Population to be Served

On page 44, the 2016 SMFP defines the service area for licensed acute care hospitals as the county where the hospital is located, with the exception of any multicounty planning areas. Thus, in this application, the service area is Mecklenburg County. Hospitals may serve residents of counties not included in their service area.

The applicant states in supplemental information that the projected patient origin for the project has not changed from what it proposed in its original application, Project I.D. #F-10075-13. Therefore, the applicant has adequately identified the population to be served.

Analysis of Need

In Section II.3, pages 11-14, the applicant discusses why the cost of the project will exceed 115 percent of the originally approved project cost, summarized as follows:

- While no decision had been made at the time the original application had been filed as to the type of analyzer to be utilized in the acute care lab, a newer model has now been selected that will cost more than previously anticipated. The selected analyzer will be identical to the one being used at CMC's off-site core lab in order to be able to provide *"…a natural back-up for the other…"*

- The newer model analyzer will require changes to utility infrastructure involving water and plumbing. These changes are complex due to the many changes made to the building's infrastructure over several decades, resulting in increased cost.

- Workflow changes to accommodate GYN cytology functions and a reconfiguration of phlebotomy services will result in minor changes to the layout of the acute care lab space, also at additional cost.

The applicant states, on page 11, that the increase in the construction costs alone account for over 125 percent of the original project's budget. The applicant further states, on page 11, that these costs are attributable, in part, to the above stated changes to the project, but are also attributable to changes in *"market conditions in the construction industry"*, particularly increases in labor costs.

The following table compares the previously approved capital cost and the proposed capital cost in this application, as reported in Section VI.4, page 30:

CMC Previously Approved and Proposed Capital Costs			
Category	**Previously Approved Cost**	**Proposed Cost**	**Difference**
Construction Costs	**$2,615,228**	**$3,515,228**	**$900,000**
Miscellaneous Costs			
Movable Equipment Purchase/Lease	$258,750	$308,750	$50,000
Furniture	$323,250	$323,250	$0
Consultant Fees			
Architect/Engineering Fees	$443,750	$533,750	$90,000
Legal and CON Fees	$50,000	$50,000	$0
Other (Admin)	$450	$450	$0
Other (Contingency)	$63,300	$63,300	$0
Subtotal Miscellaneous Project Costs	**$1,139,500**	**$1,279,500**	**$140,000**
Total Capital Costs	**$3,754,728**	**$4,794,728**	**$1,040,000**

As shown in the table above, the cost overrun is largely due to increases in construction costs, but is also due to associated architect and engineering fees, and movable equipment.

The applicant adequately demonstrates the need for the proposed cost overrun.

Projected Utilization

In Section III.2, page 20, the applicant provides the projected utilization of its acute care lab for the interim operating years, (CY2015 – CY2017), and the first three operating years of the project, (CY2018 - CY2020), as follows:

Billable Lab Procedures	**Interim Year CY2015**	**Interim Year CY2016**	**Interim Year CY2017**	**OY1 CY2018**	**OY2 CY2019**	**OY3 CY2020**	**CAGR**
Projected Utilization	6,468,669	6,834,324	7,220,649	7,628,811	8,060,046	8,515,657	5.7%

The utilization projections are a change from those projected in the original application. In Section III.2, pages 18-20, the applicant discusses the reasons for the change, summarized as follows:

In the original application, the applicant projected an annual growth rate of 7.35 percent based on the historical utilization of its laboratory services. However, its growth rate for these services has changed due to changes in the billing system and process, consolidation of multiple procedure codes to one procedure code, and the exclusion of some procedures from procedure counts that were also included in DRG payments. In addition, the applicant had previously included laboratory services utilization for several affiliate hospitals that it no

longer provides at the same pace. Therefore, the applicant's laboratory services are expected to grow at a lower rate. The applicant states, on page 20,

> *"In fact, CMC believes that its compound annual growth rate (CAGR) from CY 2013 to CY 2015 YTD (5.65 percent CAGR as shown below) is a reasonable assumption for future growth. CY 2013 is a reasonable starting point to assess future growth as the new billing system and changes to the ways procedures are counted have been consistent since that time and allow for an accurate analysis of year-over-year growth."*

The applicant provides its utilization for CY2013 – CY2015 and the CAGR for this period, in Section III.2, page 20, as follows:

Billable Lab Procedures	**CY2013**	**CY2014**	**CY2015***	**CAGR**
Actual Interim Utilization	5,795,003	6,294,780	6,468,669	5.65%

**Based on September Year-to-Date annualized.*

The applicant adequately demonstrates that the utilization projections are based on reasonable and adequately supported assumptions.

Access

In Section IV.2, page 22, the applicant states that access to its proposed services will not change from what it stated in its original application. However, in Section IV.6, page 23, the applicant states that its projected payor mix has changed based on its payor mix from CY2014. During CY2014, at least 54.5% of its billable laboratory procedures were paid for in part by Medicare and/or Medicaid. The applicant further states, on page 23, that it does not expect any changes in payor mix for the proposed project from the payor mix in CY2014.

Conclusion

In the original application, the applicant adequately identified the population to be served, demonstrated the need to renovate and consolidate its acute care laboratory services and the extent to which all residents of the service area, including underserved groups, are likely to have access to its services. However, the applicant underestimated the capital cost necessary to complete the project. In this application, the applicant adequately demonstrates the need for the proposed cost overrun. Consequently, the cost overrun application is conforming to this criterion.

(3a) In the case of a reduction or elimination of a service, including the relocation of a facility or a service, the applicant shall demonstrate that the needs of the population presently served will

be met adequately by the proposed relocation or by alternative arrangements, and the effect of the reduction, elimination or relocation of the service on the ability of low income persons, racial and ethnic minorities, women, handicapped persons, and other underserved groups and the elderly to obtain needed health care.

NA

(4) Where alternative methods of meeting the needs for the proposed project exist, the applicant shall demonstrate that the least costly or most effective alternative has been proposed.

CA

In Section II.5, pages 15-16, the applicant discusses the three alternatives considered, summarized as follows:

1. Ceasing the Project – the applicant states that this would not allow it to effectively use resources, improve throughput, or optimize patient care. Therefore, this would not be an effective alternative.

2. Not Addressing the Need for Additional Utility Infrastructure – the applicant states that the expanded utility infrastructure is needed to be able to obtain and utilize the latest, most advanced lab technology which will also serve as a back-up to CMC's off-site lab functions. Therefore, not addressing the need for additional utility infrastructure would not be an effective alternative.

3. Develop the Project as Proposed – the applicant concluded that the benefit of the proposed project justifies the additional expenditure and therefore is the most effective alternative to address the need to renovate and consolidate acute care lab functions. Therefore, it is the most effective alternative.

Furthermore, in Project I.D. #F-10075-13, the application was conforming to all other applicable statutory review criteria, and thus, is approvable. A project that cannot be approved cannot be an effective alternative. The applicant adequately demonstrates that its proposal is the least costly or most effective alternative to meet the identified need. Therefore, the application is conforming to this criterion and approved subject to the following conditions:

1. **The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall materially comply with all conditions of approval on the certificate of need for Project I.D. # F-10075-13 except as specifically modified by the conditions of approval for this application, Project I.D. # F-11123-16.**

2. **The total approved capital expenditure for Project I.D. # F-10075-13 and Project I.D. # F-11123-16 combined shall be $4,794,728.**

3. **The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall not acquire, as part of this project, any equipment that is not included in the project's proposed capital expenditure in Section VI of the application that would otherwise require a certificate of need.**

4. **Prior to issuance of the certificate of need, The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas Medical Center shall acknowledge acceptance of and agree to comply with all conditions stated herein to the Healthcare Planning and Certificate of Need Section in writing prior to issuance of the certificate of need.**

(5) Financial and operational projections for the project shall demonstrate the availability of funds for capital and operating needs as well as the immediate and long-term financial feasibility of the proposal, based upon reasonable projections of the costs of and charges for providing health services by the person proposing the service.

C

The proposed project is for a cost overrun for Project I.D. # F-10075-13. The total capital cost is now expected to be $4,794,728, an increase of $1,040,000 or 27.7% [(4,794,728/ $3,754,728) – 1 = 0.277 or 27.7%] of the approved capital cost. See Section VI, pages 28-30.

Availability of Funds

In Section VI.5, page 31, the applicant states the total capital cost of the project will be funded with accumulated reserves. In Exhibit 7, the applicant provides a letter dated January 15, 2016 and signed by the Executive Vice President and Chief Financial Officer, Carolinas HealthCare System (CHS), which documents the availability and intended use of existing accumulated cash reserves to finance the cost overrun. The amount of accumulated cash reserves to be used for the project is equivalent to the cost overrun amount of $1,040,000.

In Exhibit 8, the applicant provides the audited financial statements for The Charlotte-Mecklenburg Hospital Authority d/b/a Carolinas HealthCare System for the years ending December 31, 2013 and December 31, 2014. As of December 31, 2014, Carolinas HealthCare System had cash and cash equivalents totaling $96,271,000 with $7,213,587,000 in total assets and $4,029,263,000 in net assets (total assets less total liabilities).

Financial Feasibility

In Form C of the pro forma financial statements for CMC's Laboratory, the applicant projects that revenues will exceed operating expenses in each of the first three operating years of the project, as illustrated in the table below:

CMC Laboratory Services
Revenue and Expenses

	OY 1 CY2018	OY 2 CY2019	OY 3 CY2020
Gross Patient Revenue	$903,220,619	$982,905,378	$1,069,620,158
Deductions from Gross Patient Revenue	$662,750,773	$725,899,731	$794,819,345
Net Patient Revenue	$240,469,846	$257,005,647	$274,800,812
Total Expenses	$148,986,586	$161,645,722	$175,325,954
Net Income	$103,850,885	$108,818,658	$114,120,960

In addition, in Form B of the pro forma financial statements, the applicant projects that CMC's revenues will exceed operating expenses in each of the first three operating years of the project. The assumptions used by the applicant in preparation of the pro forma financial statements are reasonable, including projected utilization, costs, and charges. See the Financials section of the application for the assumptions used regarding costs and charges. The discussion regarding utilization found in Criterion (3) is incorporated herein by reference. The applicant adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

Conclusion

The applicant adequately demonstrates the availability of sufficient funds for the capital expenses of the project. The applicant also adequately demonstrates that the financial feasibility of the proposal is based upon reasonable projections of costs and charges. Therefore, the application is conforming to this criterion.

(6) The applicant shall demonstrate that the proposed project will not result in unnecessary duplication of existing or approved health service capabilities or facilities.

C

On page 44, the 2016 SMFP defines the service area for licensed acute care hospitals as the county where the hospital is located, with the exception of any multicounty planning areas. Thus, in this application, the service area is Mecklenburg County. Hospitals may serve residents of counties not included in their service area.

In Project I.D. # F-10075-13, the application was conforming to this criterion and no changes are proposed in this application to affect that determination. Consequently, the application is conforming to this criterion.

(7) The applicant shall show evidence of the availability of resources, including health manpower and management personnel, for the provision of the services proposed to be provided.

C

The applicant provides current staffing from CY2015 in Section V.1, page 24, and projected staffing for OY2, CY2019, in Section V.1, page 25. The following table illustrates the differences in proposed staffing from current staffing and OY2, as follows:

Proposed FTEs, CMC Acute Care Laboratory

Positions	Current # of FTEs, CY2015	Proposed # of FTEs OY2, CY2019	Difference in # of FTEs
PRN*	1.5	1.6	0.1
Aides and Attendants	60.6	65.0	4.4
Admin/Management	4.3	4.6	0.3
Supervisory	32.7	35.1	2.4
Professional	2.9	3.1	0.2
Registered Technician	140.6	150.9	10.3
Technician	87.7	94.1	6.4
Specialist	4.9	5.3	0.4
Clerical	9.7	10.4	0.7
TOTAL	**344.9**	**370.1**	**25.2**

*In supplemental information, the applicant states that PRN means *"as needed"* staff serving in aide or technician roles.

In the original application, Project I.D. #F-10075-13, the applicant proposed a higher increase in staffing in the second operating year than it is proposing in this application. For Project I.D. #F-10075-13, the applicant proposed a total of 401.9 FTE positions in CY2017, OY2, as compared to 370.1 FTE positions in CY2019, OY2, for the proposed project. In Section V.1, page 24, the applicant states that it has revised its proposed staffing for the project based on *"changes in work processes and historical and projected utilization."*

The applicant states, in Section V.1, page 24, that CMC, as the flagship hospital of Carolinas HealthCare System and having numerous resources from which to obtain staff, will be able to obtain staff when needed. In addition, the applicant states that *"additional staff will be required in the future."*

Consequently, the application is conforming to this criterion.

(8) The applicant shall demonstrate that the provider of the proposed services will make available, or otherwise make arrangements for, the provision of the necessary ancillary and support services. The applicant shall also demonstrate that the proposed service will be coordinated with the existing health care system.

C

In Project I.D. # F-10075-13, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the cost overrun application is conforming to this criterion.

(9) An applicant proposing to provide a substantial portion of the project's services to individuals not residing in the health service area in which the project is located, or in adjacent health service areas, shall document the special needs and circumstances that warrant service to these individuals.

NA

(10) When applicable, the applicant shall show that the special needs of health maintenance organizations will be fulfilled by the project. Specifically, the applicant shall show that the project accommodates: (a) The needs of enrolled members and reasonably anticipated new members of the HMO for the health service to be provided by the organization; and (b) The availability of new health services from non-HMO providers or other HMOs in a reasonable and cost-effective manner which is consistent with the basic method of operation of the HMO. In assessing the availability of these health services from these providers, the applicant shall consider only whether the services from these providers:

(i) would be available under a contract of at least 5 years duration;
(ii) would be available and conveniently accessible through physicians and other health professionals associated with the HMO;
(iii) would cost no more than if the services were provided by the HMO; and
(iv) would be available in a manner which is administratively feasible to the HMO.

NA

(11) Repealed effective July 1, 1987.

(12) Applications involving construction shall demonstrate that the cost, design, and means of construction proposed represent the most reasonable alternative, and that the construction project will not unduly increase the costs of providing health services by the person proposing the construction project or the costs and charges to the public of providing health services by other persons, and that applicable energy saving features have been incorporated into the construction plans.

NA

(13) The applicant shall demonstrate the contribution of the proposed service in meeting the health-related needs of the elderly and of members of medically underserved groups, such as medically indigent or low income persons, Medicaid and Medicare recipients, racial and ethnic minorities, women, and handicapped persons, which have traditionally experienced difficulties in obtaining equal access to the proposed services, particularly those needs identified in the State Health Plan as deserving of priority. For the purpose of determining the extent to which the proposed service will be accessible, the applicant shall show:

(a) The extent to which medically underserved populations currently use the applicant's existing services in comparison to the percentage of the population in the applicant's service area which is medically underserved;

C

In Section IV.6, page 23, the applicant states that it has provided a revised projected payor mix based on its payor mix for acute care laboratory services for CY2014. Therefore, CMC's historical payor mix is illustrated as follows:

CMC Acute Care Lab Payor Mix
CY2014

Payor	**Percent**
Self Pay/Other	9.4%
Medicare/ Medicare Managed Care	34.7%
Medicaid	19.8%
Managed Care/ Commercial	36.1%
Total	**100.0%**

In addition, the applicant's original application, Project I.D. #F-10075-13, was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination. Consequently, the application is conforming to this criterion.

(b) Its past performance in meeting its obligation, if any, under any applicable regulations requiring provision of uncompensated care, community service, or access by minorities and handicapped persons to programs receiving federal assistance, including the existence of any civil rights access complaints against the applicant;

C

In Project I.D. # F-10075-13, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the application is conforming to this criterion.

(c) That the elderly and the medically underserved groups identified in this subdivision will be served by the applicant's proposed services and the extent to which each of these groups is expected to utilize the proposed services; and

C

In Section IV.6, page 23, the applicant provides a revised, projected payor mix from its original application stating that it is based on its payor mix for acute care laboratory services for CY2014, illustrated as follows:

CMC Acute Care Lab Payor Mix
CY2019

Payor	**Percent**
Self Pay/Other*	9.4%
Medicare/ Medicare Managed Care	34.7%
Medicaid	19.8%
Managed Care/ Commercial	36.1%
Total	**100.0%**

**Other includes worker's compensation and unspecified payors.*

The applicant demonstrates that medically underserved populations will have adequate access to the proposed services. Moreover, the applicant's original application, Project I.D. #F-10075-13, was conforming to this criterion and the applicant proposes no changes in the current application that would affect that determination. Consequently, the application is conforming to this criterion.

(d) That the applicant offers a range of means by which a person will have access to its services. Examples of a range of means are outpatient services, admission by house staff, and admission by personal physicians.

C

In Project I.D. # F-10075-13, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the application is conforming to this criterion.

(14) The applicant shall demonstrate that the proposed health services accommodate the clinical needs of health professional training programs in the area, as applicable.

C

In Project I.D. # F-10075-13, the application was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the application is conforming to this criterion.

(15) Repealed effective July 1, 1987.
(16) Repealed effective July 1, 1987.
(17) Repealed effective July 1, 1987.
(18) Repealed effective July 1, 1987.

(18a) The applicant shall demonstrate the expected effects of the proposed services on competition in the proposed service area, including how any enhanced competition will have a positive impact upon the cost effectiveness, quality, and access to the services proposed; and in the case of applications for services where competition between providers will not have a

favorable impact on cost-effectiveness, quality, and access to the services proposed, the applicant shall demonstrate that its application is for a service on which competition will not have a favorable impact.

C

On page 44, the 2016 SMFP defines the service area for licensed acute care hospitals as the county where the hospital is located, with the exception of any multicounty planning areas. Thus, in this application, the service area is Mecklenburg County. Hospitals may serve residents of counties not included in their service area.

Project I.D. # F-10075-13 was conforming to this criterion, and the applicant proposes no changes in the current application that would affect that determination. Consequently, the application is conforming to this criterion.

(19) Repealed effective July 1, 1987.

(20) An applicant already involved in the provision of health services shall provide evidence that quality care has been provided in the past.

C

According to the files in the Acute and Home Care Licensure and Certification Section, DHSR, one incident occurred at one facility that The Charlotte Mecklenburg Hospital Authority owns and operates in the State of North Carolina within the eighteen months immediately preceding submission of the application through the date of this decision, for which any sanctions or penalties related to quality of care were imposed by the State. The facility is now back in compliance. After reviewing and considering information provided by the applicant and by the Acute and Home Care Licensure and Certification Section, and considering the quality of care provided at all 22 facilities, the applicant provided sufficient evidence that quality care has been provided in the past. Therefore, the application is conforming to this criterion.

(21) Repealed effective July 1, 1987.

(b) The Department is authorized to adopt rules for the review of particular types of applications that will be used in addition to those criteria outlined in subsection (a) of this section and may vary according to the purpose for which a particular review is being conducted or the type of health service reviewed. No such rule adopted by the Department shall require an academic medical center teaching hospital, as defined by the State Medical Facilities Plan, to demonstrate that any facility or service at another hospital is being appropriately utilized in order for that academic medical center teaching hospital to be approved for the issuance of a certificate of need to develop any similar facility or service.

NA